Attachment 3

Elements of a Basic Quality System for Regulatory Compliance	What regulation covers some of or the entire element?	What isn't covered by the regulatory system? Should it or can it be covered by the regulations?	Recommendations
Standard	Part 145		
Working group assignment	The Federal Aviation Administration (FAA) is issuing this notice to advise the public of two meetings of the Aviation Rulemaking Advisory Committee to discuss Air Carrier and General Aviation Maintenance Issues. Specifically, the committee will discuss two tasks concerning **quality assurance** and **ratings** for aeronautical repair stations. **DATE**		TCCA AWM 501 Definition of Quality Assurance: "Quality assurance" means a planned and systematic pattern of all actions necessary to provide confidence that aeronautical products will conform to approved design data and be in a condition for safe operation.
System for complying to the standards (often not always written up in a manual that addresses each of the elements of the standard)	145.45	145.45 speaks of an "inspection system that will produce satisfactory quality control" Should there be discussion of quality assurance?	*Require the repair station to have a manual (kept current) that explains how it complies with each FAA regulation that applies to it. This would be a continuation of the compliance plan document usually submitted as a part of the application* **Inspection manual should describe system by which the following three objectives are complied with.** **Objective 1 of a quality system:** Compliance to FARs This is accomplished by providing clear policy and procedure for each requirements of FAR 145. These are contained and/or enabled within the "Repair Station Manual" document. Any changes in the FARs should cause an amendment to the "Repair Station Manual", to describe

			company system changes. **Objective 2 of a quality system:** Quality (assurance) System should ensure the repair station is in compliance to it's "Repair Station Manual" This is where the internal audit comes in. There should be scheduled and random audits. i) The scheduled audit (yearly?) should be thorough enough to ensure company personnel are in compliance with company policy and procedures. ii) The random audits should apply to each product line and should ensure the final product is in compliance to airworthiness requirements. Note: Individuals certifying maintenance are exercising a quality control measure directly applicable to the maintenance they have accomplished. **Objective 3:** Any discrepancy discovered during activities of Objective 1 or 2 should be captured on an audit finding form. All findings should be closed loop, where corrective action is monitored to ensure it was effective, and to ensure there are no repeats of the non-conformance.*for the 145 certificate*
Quality policy	145.57(a)	145.57(a) is one of the many conditions for the issuance of a Repair Station Certificate. 145.211(a) Should this paragraph also	**Quality policy should be in keeping with the objectives described above.**

		address quality assurance?	Note: Some of the quality characteristics that make up the specifications of the final product may not be measurable by review at time of certification. **E.g.1:** Compliance to Human Factors training regulations. Compliance to a requirement to have a system where "maintenance errors" are recorded as findings, requiring human factors analysis **E.g. 2:** Compliance to drug and alcohol requirements. Note: The purpose of a quality system wholly focused on end product reviews would be to capture defective products. In aviation, defective products lead to accidents.
Organization	145.39 145.75 145.2 – Part 121, subpart L, except for 121.363, 121.369, 121.373 and 121,379	Conditions that must be met. This could be defined as "quality characteristics" of the approved organization.	There should be independence between the individuals that accomplish Quality System reviews and from those that provide corrective action for any finding uncovered during these reviews.
Management review		Conditions that must be met. This could be defined as "quality characteristics" of the approved organization.	The accountable manager must be made aware of any audit finding that can be directly linked to an aviation safety concern.
General	??		
Quality system procedures	145.45	Should there be text that covers quality assurance?	**Procedures as described below.** Objective 1:

			i) Monitoring FARs for changes. Accomplishing this objective is accomplished through the Repair Station Manual FAA amendment procedure Objective 2: i) Internal audit, documented process (detailed check sheets for each quality characteristic that make up the maintenance specifications) should provide for consistent scope, depth and detail of the review. ii) Random audits, documented process (detailed check sheets for each product line where quality characteristics are measured and recorded) should be for all product lines, when and where the maintenance is accomplished. The frequency and quantity of these random audits should demonstrate a good level of confidence in the final product. iii) "Quality Control" accomplished by the individuals certifying maintenance. All maintenance is certified one way or another. The

			individual that certifies the maintenance must be aware that there cannot be any compromise on safety. Procedures for these certifications must be in compliance to Repair Station policy. Objective 3: i) Approved organization must develop an audit finding form, that includes four elements: (a) standard, (b) problem, (c) planned corrective action, (d) follow up to ensure corrective action is effective. ii) audit findings can be generated by any individual that works for the approved organization iii) audit findings could be the result of periodic audit, quality control review or random sampling iv) audit findings are controlled by the quality system personnel v) audit finding corrective action is the responsibility of the person that designs the system (assures independence) vi) corrective action must be

			monitored to ensure the change was effective. vii) start of an internal audit period should begin with the review of findings of the previous audit period. This is to capture repeat findings. end of an internal audit period should include an executive summary that provides insight of the type of findings experienced, and a description of systemic changes taken to prevent reoccurrence.
Quality planning	145.39(a) and (b) 145.53	Conditions that must be met. This could be defined as "quality characteristics" of the approved organization.	Objective 1: as needed Objective 2: i) yearly (?) for internal audit ii) ongoing for random audit iii) ongoing for quality control review of final products by those that certify them. Objective 3: ongoing
Contract review		Conditions that must be met. This could be defined as "quality characteristics" of the approved organization.	The Repair Station should have Quality System measures to ensure contracted maintenance is accomplished in accordance with applicable airworthiness requirements.
Design control	SFAR-36		
Document and data control	145.2 145.57(a)	Conditions that must be met. This could be defined as "quality characteristics" of the approved organization.	Quality system records must reflect all that is accomplished, must be protected from loss or theft, and (suggestion) must be kept for at least 3 years. (It should be the same as the largest possible FAA audit frequency)
Purchasing	???		
Control of customer-	145.2	Conditions that must be met. This could	Individual that installs the

supplied product		be defined as "quality characteristics" of the approved organization.	aeronautical products on the aircraft, makes the final decision
Product identification and traceability		Conditions that must be met. This could be defined as "quality characteristics" of the approved organization.	Individual that installs the aeronautical products on the aircraft, makes the final decision.
Process control	43.13(a) 145.57(a)	Should there be discussion of Quality Assurance?	Process for quality system reviews must ensure thoroughness and consistency.
Inspection and test status	145.45(c-f) 43.9 43.11	Should there be discussion of Quality Assurance?	Compliance to Repair Station Manual must be assured Compliance to airworthiness requirements must be assured
Control of nonconforming product	145.35(d)	Conditions that must be met. This could be defined as "quality characteristics" of the approved organization.	
Handling, storage, packaging, delivery	145.2 145.47 145.49	Conditions that must be met. This could be defined as "quality characteristics" of the approved organization.	
Control of quality records	145.43 145.49 145.61 145.79	Conditions that must be met. This could be defined as "quality characteristics" of the approved organization.	Delineated in the Repair Station Manual Records must be protected from damage or loss, and must be kept for 3 years?
Training	145.2	Conditions that must be met. This could be defined as "quality characteristics" of the approved organization.	All employees must be trained on applicable portions of the Repair Station Manual
Servicing	145.57(a) 145.2	Conditions that must be met. This could be defined as "quality characteristics" of the approved organization.	
Statistical techniques	43.13(b)		

Audits to assure that the system meets desired standards (compliance with the standard—audit checklist should be developed from the standard) Internal quality audits	FAA surveillance 121.373 audits	Should there be discussion of Quality Assurance?	*145 performs self-audits; third party performs audits; standardize records of the audits* Quality System objective 2 described above, applies Third party may perform the audit review, however, the corrective action and follow up to any finding must remain with the approved organization.
Review of the audit results (identify failures and inadequacies)	FAA usually orally briefs repair station following audit; a written exposition of deficiencies is provided		*Require the repair station to review its own audits or third party audits and maintain records thereof* Quality System objective 3 described above, applies
Identification and implementation of improvements Corrective and preventative action	Civil penalty system penalizes those who are found deficient; those who correct deficiencies may be eligible for administrative action	There should be text that mandates verification that any corrective action taken is verified to have been effective. There should be a means to capture recurring findings.	*Require correction of identified regulatory deficiencies (would be redundant since the regulations already require these elements, although a time limit on correction could be added)* Quality System objective 3 described above, applies